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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,796	05/28/2004	Michael A. Slivka	101896-251 (DEP5318)	3795

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EXAMINER	
HOFFMAN, MARY C	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
09/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/709,796	SLIVKA ET AL.	
	Examiner	Art Unit	
	MARY HOFFMAN	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *13,14,19,20,24 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-18,21-23,25-31 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/08/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15, 18, 21-23, 25-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Shih et al. (US 6,136,002).

Shih et al. disclose a device for treating spinal deformities, comprising a spinal anchoring element (see ref. #10, FIGS. 2-3) adapted to seat first (FIG. 2, ref. #40, right) and second (FIG. 2, ref. #40, left) spinal fixation elements at a distance spaced apart from one another; a bore (ref. #124) and a closure mechanism (ref. #14) adapted to mate to the spinal anchoring element to lock

each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element. The spinal anchoring element a fastening element (ref. B.) and includes a first recess (ref. #126, right) adapted to receive a first spinal fixation element, and a second recess (ref. #126, left) spaced a distance apart from the first recess and adapted to receive a second spinal fixation element. The closure mechanism is capable of receiving a locking mechanism that engages the bore (this claim recitation is being interpreted as functional language, and the Shih et al. reference need merely be capable of performing the claimed function). The spinal anchoring element includes a central portion (ref. #130) positioned between the first and second recesses and {adapted to receive a fastening element for mating the anchoring element to bone- functional language}. The central portion includes a bore (ref. "H") extending therethrough {for receiving a fastening element- functional language}. The closure mechanism includes a central portion (see hole in ref. #14) adapted to receive a locking mechanism for mating the closure mechanism to the spinal anchoring element. The device further comprises a fastening element (ref. "B") for mating the spinal anchoring element to bone, and a locking mechanism (ref. "S") for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw, and the locking mechanism comprises a setscrew. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The

device further comprises a bone-engaging member, a spike (ref. #122), extending distally from the inferior surface of each of the first and second end portions adapted to extend into bone to prevent rotation of the spinal anchoring element. The closure mechanism includes a first end portion adapted to lock a spinal fixation element within the first recess, and a second end portion adapted to lock a spinal fixation element within the second recess. The device further comprises first and second spinal fixation elements (ref. #'s 40) adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape. A plurality of spinal anchoring devices adapted to mate to a plurality of vertebrae and to engage the first and second spinal fixation elements such that the first and second spinal fixation elements can be tensioned between the plurality of spinal anchoring devices to adjust a position of the plurality of vertebrae in both a sagittal plane and a coronal plate when the plurality of spinal anchoring devices are implanted in a plurality of vertebrae. The system further comprises a bore extending through the closure mechanism and spinal anchoring element {for receiving a fastening element adapted to mate the spinal anchoring element to bone- functional language}. The bore in the closure mechanism and spinal anchoring element is positioned between the first and second recesses.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12, 15, 18, and 21-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Assaker et al. (US 7,008,426).

Assaker et al. disclose a device (FIG. 9) for treating spinal deformities, comprising a spinal anchoring element (bottom part of ref. #6) adapted to seat first and second spinal fixation elements (ref. #2 3) and at a distance spaced apart from one another, the spinal anchoring element having a bore (ref. #30) extending therethrough; a fastening element (ref. #8) adapted to extend through the bore to mate the spinal anchoring element to bone; and a closure mechanism (top part of ref. #6) adapted to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, the closure mechanism adapted to receive a locking mechanism (ref. #10) that directly engages the bore. The spinal anchoring element includes a first recess (ref. #13) adapted to receive a first spinal fixation element, and a second recess (ref. #52) spaced a distance apart from the first recess and adapted to receive a second spinal fixation element. The spinal anchoring element includes a central portion positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion adapted to receive a locking mechanism for mating the closure mechanism to the spinal anchoring element. The device further comprises a locking mechanism for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw, and the locking mechanism comprises a set

screw. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion adapted to lock a spinal fixation element within the first recess, and a second end portion adapted to lock a spinal fixation element within the second recess. The device further comprising first and second spinal fixation elements adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shih et al. (US 6,136,002) in view of Paul et al. (US 2004/0236327).

Shih et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Shih et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker et al. (US 7,008,426) in view of Paul et al. (US 2004/0236327).

Assaker et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Assaker et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Claims 10-11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker et al. (US 7,008,426) in view of Shih et al. (US 6,136,002).

Assaker et al. disclose the claimed invention except for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions.

Shih et al. disclose bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions for gripping bone.

It would have been obvious at the time the invention was made to construct the fixation elements of Assaker et al. with bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions in view of Shih et al. to grip bone.

Response to Arguments

Applicant's arguments filed 02/07/2008 have been fully considered but they are not persuasive. Applicant argues that the Shih et al reference does not anticipate or suggest the amended claim language. It is noted that the claim recitation "adapted to receive a locking mechanism that directly engages the bore" is being interpreted as functional language, and the Shih et al. reference need merely be capable of performing the claimed function. With regard to the statements of intended use and other functional statements, i.e. "adapted to" recitations in the claims and see "{functional language}" in above explanation, they do not impose any structural limitations on the claims distinguishable over Shih et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary

that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733